



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA-2017-N-6539]

Medical Devices; Radiology Devices; Classification of the Absorbable Perirectal Spacer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the absorbable perirectal spacer into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the absorbable perirectal spacer's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on April 1, 2015.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD, 20993-0002, 301-796-5866, steven.tjoe@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the absorbable perirectal spacer as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and

Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence").

Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 1, 2014, Augmenix, Inc. submitted a request for De Novo classification of the SpaceOAR System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 1, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 892.5725. We have named the generic type of device absorbable perirectal spacer, and it is identified as a device composed of biodegradable material that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Absorbable Perirectal Spacer Risks and Mitigation Measures

| Identified Risks | Mitigation Measures/21 CFR Section |
|--|--|
| Device functional failure or the device is unable to maintain space stability during the course of radiation therapy | Special Controls (1)(i) (21 CFR 892.5725(b)(1)(i)), (1)(ii) (21 CFR 892.5725(b)(1)(ii)), (1)(iv) (21 CFR 892.5725(b)(1)(iv)), and (1)(vi) (21 CFR 892.5725(b)(1)(vi)) |
| Prolonged or delayed procedure | Special Controls (1)(iii) (21 CFR 892.5725(b)(1)(iii)), (1)(iv) (21 CFR 892.5725(b)(1)(iv)), (2) (21 CFR 892.5725(b)(2)), and (3) (21 CFR 892.5725(b)(3)) |
| Needle penetration and/or spacer material injection into bloodstream, bladder, prostate, rectal wall, rectum, or urethra | Special Controls (1)(iv) (21 CFR 892.5725(b)(1)(iv)), (2) (21 CFR 892.5725(b)(2)), and (3) (21 CFR 892.5725(b)(3)) |
| Incomplete absorption | Special Controls (1)(iii) (21 CFR 892.5725(b)(1)(iii)), (1)(iv) (21 CFR 892.5725(b)(1)(iv)), and (1)(vii) (21 CFR 892.5725(b)(1)(vii)) |
| Infection or local tissue inflammatory reactions | Special Controls (1)(iv) (21 CFR 892.5725(b)(1)(iv)), (1)(v) (21 CFR 892.5725(b)(1)(v)), (1)(vi) (21 CFR 892.5725(b)(1)(vi)), (1)(vii) (21 CFR 892.5725(b)(1)(vii)), and (3) (21 CFR 892.5725(b)(3)) |
| Pain or discomfort associated with spacer | Special Controls (1)(iv) (21 CFR 892.5725(b)(1)(iv)) and (3) (21 CFR 892.5725(b)(3)) |
| Urine retention, bleeding, rectal mucosal damage, ulcers, necrosis, constipation, or rectal urgency | Special Controls (1)(iii) (21 CFR 892.5725(b)(1)(iii)), (1)(iv) (21 CFR 892.5725(b)(1)(iv)), (1)(vii) (21 CFR 892.5725(b)(1)(vii)), (2) (21 CFR 892.5725(b)(2)), and (3) (21 CFR 892.5725(b)(3)) |

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary

special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120; the collections of information in part 820 have been approved under OMB control number 0910-0073; and, the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892--RADIOLOGY DEVICES

1. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 892.5725 to subpart F to read as follows:

§ 892.5725 Absorbable perirectal spacer.

(a) *Identification.* An absorbable perirectal spacer is composed of biodegradable material that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The premarket notification submission must include methodology and results of the following non-clinical and clinical performance testing. For all clinical investigations used to support premarket notification submissions for this type of device, line listings of the study data must be provided.

(i) Performance bench testing must demonstrate appropriate perirectal space creation and maintenance for the duration of prostate radiotherapy.

(ii) Performance bench testing must demonstrate that therapeutic radiation levels do not alter the performance of the device.

(iii) Performance in vivo testing must demonstrate appropriate deployment of spacer as indicated in the accompanying labeling, and demonstrate appropriate expansion and absorption characteristics in a clinically relevant environment.

(iv) Clinical study must demonstrate appropriate spacer stability and lack of migration for the entire course of radiotherapy, complete absorption, and lack of long term toxicity.

(v) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the spacer.

(vi) Shelf-life testing must demonstrate the stability of the physical characteristics of the spacer throughout the shelf-life as indicated in the accompanying labeling.

(vii) The device must be demonstrated to be biocompatible.

(2) The risk management activities performed as part of the manufacturer's § 820.30 design controls must document an appropriate end user initial training program which will be offered as part of efforts to mitigate the risk of failure to correctly operate the device, including, but not limited to, documentation of an appropriate end user initial training program on the proper spacer deployment technique.

(3) The device labeling must include the following:

(i) A detailed summary of reported or observed complications related to the use of the device;

(ii) Appropriate warnings;

(iii) Detailed instructions for system preparations and detailed implant procedure instructions; and

(iv) An expiration date that is supported by performance data as specified in paragraph (b)(1)(vi) of this section.

Dated: January 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.